

Remarks

This paper is responsive to the Office Action mailed June 30, 2004, setting an initial due date of September 30, 2004. This paper is timely filed and no fee is required.

With this Amendment, Applicant cancels claims 2-5, 9, and 21 and adds new claims 23-28. Claims 1 and 23-28 are pending in this application. Applicant notes that the claims that had been previously deemed withdrawn are now canceled.

Information Disclosure Statement

On January 3, 2001, Applicant filed an Information Disclosure Statement in this application. As of this date, Applicant has not received an initialed Form PTO-1449. Applicant respectfully requests the Office consider the Information Disclosure Statement that was timely filed on January 3, 2001, and return the Form PTO-1449, initialed, thereby indicating the Office's consideration.

Claim Objections

The Office objects to claim 1 as encompassing non-elected subject matter. In response, Applicant has amended claim 1 to recite elements that clearly place its subject matter within the scope of Group I. Applicant submits that the amendment renders moot the objection.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Office rejects claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for the recitation of “mature” and “soluble,” alleging that the distinction is unclear. Applicant respectfully submits that claim 3 is sufficiently definite and that the specification clearly describes the difference between “mature” and “soluble” proteins. Nevertheless, Applicant has canceled claim 3 and respectfully submits that the amendment renders moot the rejection.

Claim Rejections – 35 U.S.C. § 101

The Office rejects claims 4 and 5 under 35 U.S.C. § 101, alleging that the claims are directed to non-statutory subject matter. Applicant respectfully submits that the claims, as written, define statutory subject matter. Nevertheless, Applicant has canceled claims 4 and 5, and the rejection is moot.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office rejects claims 1, 2, 4, 5, and 9 under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the written description requirements, and claims 1, 2, 4, 5, 9, and 21 under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the enablement requirements.

Applicant respectfully submits that the written description and requirements are satisfied with regard to claim 1. Claim 1 is directed to: “A method for detecting DESC1 gene expression in a sample from the presence of at least one of squamous cell carcinoma and prostate cancer in a subject comprising: providing a tissue sample from the subject; and assaying for expression of the DESC1 gene in the sample, using at least one nucleic acid; wherein reduced DESC1 expression is indicative of the presence of at least one of squamous cell carcinoma and prostate cancer.”

The claimed invention is specifically described and enabled, for example, by Examples 1, 2, 3, and 5. In each Example, the method indicated lower levels of DESC1 expression in the cancerous tissue or cells compared to normal tissue or cells. (“The results, shown in Figure 3A, showed lower levels of expression of DESC1 . . .” (Example 1); “As shown in Fig. 3B, expression of DESC1 was lower . . .” (Example 2); “As shown in Figure 2, DESC1 was

expressed at a high level . . .” (Example 3); and “The results show lack of DESC1 expression . . .” (Example 5).)

Thus, the claimed invention is very clearly described and enabled. Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Priority and Claim Rejections – 35 U.S.C. § 102

The Office states that a description of SEQ ID NO: 3 and 4 is not seen in Applicant’s earliest priority application, U.S. Provisional Application No. 60/122,747, and concludes that Applicant is only entitled to a priority date of November 1999. The Office then asserts that claims 1-5, 9, and 21 are rejected under 35 U.S.C. § 102(e) over Baker et al. (U.S. Patent Application Publication No. 2003/0073129, with “priority to at least 10/98”).

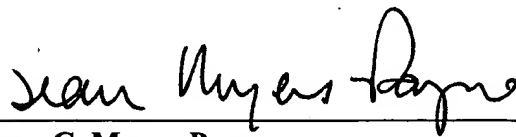
Applicant has amended claim 1 and canceled claims 2-5, 9, and 21. Amended claim 1 is directed to “A method for detecting DESC1 gene expression in a sample from the presence of at least one of squamous cell carcinoma and prostate cancer in a subject comprising: providing a tissue sample from the subject; and assaying for expression of the DESC1 gene in the sample, using at least one nucleic acid; wherein reduced DESC1 expression is indicative of the presence of at least one of squamous cell carcinoma and prostate cancer.” Applicant respectfully submits that Baker et al. makes no reference to a correlation between reduced DESC1 expression and the presence of at least one of squamous cell carcinoma and prostate cancer. For at least this reason, claim 1 is not anticipated by Baker et al.

Given the cancellation of claims 2-5, 9, and 21, and that fact that Baker et al. does not anticipate claim 1, Applicant respectfully requests withdrawal of the anticipation rejection.

If there is any fee due in connection with the filing of this Response, please charge the fee to our Deposit Account No. 03-0172.

Respectfully submitted,

Date: September 27, 2004

A handwritten signature in cursive script, reading "Sean Myers-Payne", written over a horizontal line.

Sean C. Myers-Payne

Reg. No. 42,920

(614) 621-7754

(614) 621-0010 (fax)

smyers-payne@calfee.com